



A4

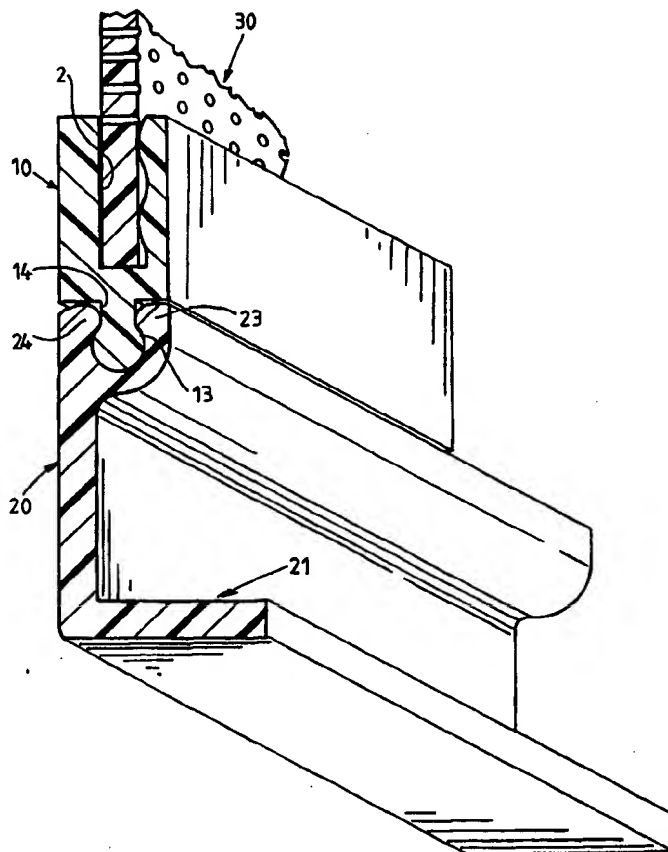
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 5/05		(11) International Publication Number: WO 98/32402
A1		(43) International Publication Date: 30 July 1998 (30.07.98)
(21) International Application Number: PCT/BE98/00010 (22) International Filing Date: 23 January 1998 (23.01.98) (30) Priority Data: 9700072 23 January 1997 (23.01.97) BE (71) Applicant (for all designated States except US): ORFIT INDUSTRIES [BE/BE]; Vosveld 9A, B-2110 Wijnegem (BE). (72) Inventor; and (75) Inventor/Applicant (for US only): CUYPERS, Steven [BE/BE]; Swaenebeeklaan 39, B-2970 's Gravenwezel (BE). (74) Agents: VAN CUTSEM, Paul et al.; S.A. Bureau Vander Haeghen N.V., Rue Colonel Bourg 108A, B-1030 Bruxelles (BE).		(81) Designated States: AL, AM, AT (Utility model), AU, BA, BG, BR, CA, CH, CN, CU, CZ, DE (Utility model), DK (Utility model), EE, ES (Utility model), FI (Utility model), GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MX, NO, NZ, PL, PT (Utility model), RO, RU, SG, SI, SK, SL, TJ, TR, TT, UA, US, UZ, VN, YU, Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Dutch).</i>

(54) Title: FIXATION SYSTEM FOR AN IMMOBILISATION ELEMENT OF A PATIENT

(57) Abstract

Fixation system for an immobilisation element of a patient, in particular a low-temperature immobilisation element comprising an attachment profile (1), one side of which is provided with a slot (11) for accommodating the said immobilisation element (30) therein, and the other side of which is provided with a fixing element (21) for interacting in a fixed manner with a base (40) as a support for the patient, distinguished by the fact that the said attachment profile (1) comprises two parts (10, 20) which can be detached from one another and which can be coupled together by means of coupling members (12, 22), which are respectively provided for this purpose on each of the two parts (10, 20), the said one part (10) being produced from a high-temperature plastic material which is non-deformable at the working temperature.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

FIXATION SYSTEM FOR AN IMMOBILISATION ELEMENT OF A
PATIENT

Field of use

5

This invention relates to a fixation system for an immobilisation element of a patient, in particular a low-temperature immobilisation element.

10

Background of the invention

Immobilising a patient or a part of a patient's body during radiotherapy, radiological examination and/or radiodiagnostics, or during stereotactic surgery on the one hand improves the quality of these methods of medical treatment and examination as a result of increased efficiency and accuracy, and on the other hand increases the comfort of the patient.

20

Prior art

The available systems comprise, on the one hand, a masking sheet material which is moulded over the patient, and on the other hand a base, to which the moulded masking sheet is joined. As a result, the patient and/or the relevant part of the patient's body is immobilised. A description is given below of systems used to date: a system using a hook-and-loop strip, in which the loop strip is pulled taut over the patient and is attached to the hook strip on the base; a system using a so-called high-temperature plastic material (HTTP), in which firstly a negative impression of the patient is taken using plaster of Paris, then a positive mould is made in plaster of Paris from this impression, and the plastic is moulded over this positive mould by means of a vacuum forming technique. The resultant plastic element is then placed over the patient and attached to the base; a system using a

40

2

patient and attached to the base; a system using a thermosetting, synthetic plaster bandage which is moulded over the patient and is attached to the base; and also a system using a so-called "bite block" system, in which on one side a small block is placed in the mouth of the patient, and the patient has to bite on this block, and on the other side a connecting piece situated on the block is attached to the base; a system in which a cushion in a soft state is arranged around the patient and is then hardened. This hardening can be carried out by chemically curing the content of the cushion or by withdrawing the air from the cushion so that the remaining content of the cushion hardens. This cushion is then fastened to the base.

Presently, much use is being made of a system in which a so-called low-temperature plastic film (LTTP) or sheet is moulded directly onto the patient in the soft state and then hardens in order to form a so-called masking sheet. The said soft state is reached by introducing the material into an environment at a relatively moderate working temperature. There are various low-temperature plastic materials available for the said masking sheets, as well as various base moulds or base plates to which the low-temperature plastic mould or mask can be joined.

Also known is a system in which a high-temperature plastic element is attached to the low-temperature plastic masking sheet, in the form of a profile which remains hard during the activation of the LTTP material, consisting in plasticizing this material. For the profile, on the one hand existing high-temperature thermoplastic materials, and on the other hand high-temperature thermosetting plastic materials are used in combination with carbon fibres.

3

However, the abovementioned existing systems exhibit drawbacks, which are explained in their respective order below.

5 In the first known system, the patient is only immobilized to a very limited extent, since this system is 2-dimensional and surrounds only a very limited area of the body part to be immobilized. This is because the loop strip has a limited width.

10

The next system does not allow direct immobilization of the patient. The system is laborious, time-consuming to use, uncomfortable for the patient and requires expensive equipment and a plurality of people.

15 Moreover, the high-temperature plastic material cannot be remoulded.

The chemical reaction of the further known system entails an exothermic reaction, which is uncomfortable
20 for the patient. Moreover, various layers are moulded unevenly above one another, resulting in differences in thickness and density in the mould, which interfere with the emitted radiation, resulting in a lack of accuracy.

25

The next known system is a 2-dimensional mould, which only provides a limited degree of immobility and is thus uncomfortable for the patient.

30 The further known system is 2-dimensional and large, the chemical system producing an exothermic reaction and entailing a laborious operating procedure, and the vacuum system exhibiting poor dimensional stability during subsequent sessions owing to the lack of vacuum
35 caused by air penetrating into the system.

The various existing systems using purely LTTP have the problem that the mould is attached to the base at only two points, so that the accuracy is not sufficiently

high. Two people are required in order to effect the activation and shaping of the low-temperature plastic. For a further known system, two people are required here. Owing to the thickness tolerance in the low-temperature plastic, the fixing part does not always fit equally easily into the base. In yet a further system, two people are also required and it can only be employed on one base system. In the known case of a so-called U-frame, the so-called tent mould of the low-temperature plastic means that the body part is not completely enclosed, so that it remains movable, which causes a lack of accuracy.

Finally, with regard to the last known case, the high-temperature plastic fixing profiles can in each case be used on only one system. A fixation profile which is known here has a relatively high density, which represents a drawback in those cases in which the said profile is situated in the field of irradiation.

It was thus desired firstly to eliminate the problem of the edges of the low-temperature plastic masking sheet becoming soft during the activation. To this end, these edges are made from a high-temperature plastic material which remains hard during the activation and can be fixed directly in or on the base plate, while the low-temperature plastic has in the meantime become soft. This resulted in a profile which on one side is attached to the low-temperature plastic masking sheet and on the other side fits into the base plate. The result was a fixing means which comprises, on the one hand, a single-piece profile made of low-temperature plastic material and, on the other hand, a piece of high-temperature plastic material, which are permanently joined to one another.

However, two important limitations are associated with this solution. Firstly, the shape of the single-piece profile can only be used on a single type of base

plate. Furthermore, owing to the fact that the profile is permanently joined to the low-temperature plastic masking sheet, the use is moreover limited to that one low-temperature plastic material or that one low-temperature plastic mould or masking sheet to which the profile in question is attached.

Object of the invention

10

The object of this invention is to alleviate the abovementioned drawbacks.

Summary of the invention

To achieve this object, the system according to the invention comprises a fixation profile with two parts which can be detached from one another, one side of which profile is provided with a slot for accommodating the said immobilization element therein, and the other side of which profile is provided with a fixing element for interacting in a fixed manner with a base as a support for the patient. One part is produced from a high-temperature plastic material which is non-deformable at the working temperature. Both parts can be coupled together by means of coupling members which are provided for this purpose.

The system according to the invention thus comprises a fixation system which has two parts, where one part rests on or can even be attached by the user to the immobilization element which is placed over that part of the body which is to be immobilized, and where the other part can on one side be detachably connected to the said one part and on the other side can have different shapes which are such that any specified mould fits into or onto a given base plate.

6

The fixation system according to the invention therefore enables an immobilization masking sheet to be fixed to base plates of various types. Moreover, in the event that a low-temperature plastic material is used, this low-temperature plastic masking sheet can be placed completely in the heating medium without the operator having to hold the mould. The heating medium may, for example, be formed by a water tank or an oven.

Further characteristics and features of the fixation system according to the invention are defined in the subclaims.

An exemplary embodiment is described in more detail below with reference to the enclosed drawings.

Brief description of the figures

Figures 1 and 2 respectively show a perspective view and a cross-section of the fixation system according to the invention, in the coupled state and with the parts detached from one another, respectively.

Figure 3 is a diagrammatic plan view of a patient to be treated who has been placed on a support table with a fixing plate.

Description

The fixation system represented in Figures 1 and 2 comprises a profile which comprises two parts 10, 20 which can be detached from one another and are shaped in such a way that they can be pushed onto one another so that the two parts 10, 20 can be joined together and detached again easily while nevertheless ensuring a strong and reliable connection in the joined state (not shown).

This is achieved in a very satisfactory manner by means of the illustrated shape of the respective ends 19, 29 of the two parts 10, 20, which allows these parts to be pushed onto one another. The holding part 10 has a fixed shape and is adhesively bonded to the fixing masking sheet 30 by means of a joining agent 2, such as for example glue, which ensures that the two parts 30, 2 remain stuck to one another during the activation.

10

However, part 20 may take various forms, in each case fitting along one side 29 over the holding part 10 and along the other side 21 into, onto or over a fixing plate 40 of a given form.

15

On the holding side 11, the holding part 10 is in the shape, for example, of a U which is pushed over the said low-temperature plastic masking sheet 30 and is adhesively bonded by means of the said bonding agent 2, which ensures that the low-temperature plastic masking sheet remains stuck during the activation. A slot 11 is formed on the holding side for holding the masking sheet 30, and the width of opening 11 may differ depending on the thickness of the masking sheet 30. On its underside, the holding part 10 has an external bar-like projecting part or protrusion 12 which fits in a corresponding coupling side 22 of the second part 20.

The second part 20 is thus provided on the said coupling side with a groove 22, which fits tightly over the said protrusion 12 of the holding part 10. Preferably, the groove 22 has a constriction 25 which forms a narrowed section 26 of the groove 22. This constriction 25 exerts a retaining action on the said protrusion 12 and makes it possible to snap the holding part 10 into the groove.

The opposite side 21 of the engagement part 20 may have various forms which are such that part 20 can fit into

various types of fixing plates 40. This side may, for example, have an L-shape 21 which is known per se, so that it fits into the fixing plates 40 of our existing HP system. However, the said side may also be straight
5 with three openings, so that it fits over the small pins on the fixing plate of a conventional system.

The holding part 10 and the engaging part 20 can thus be quickly connected to one another in a reliable but
10 nevertheless releasable manner without the two parts being able to move with respect to one another once they have been snapped or pushed into one another unless a considerable force is exerted on them. This avoids the two parts 10, 20 from becoming detached
15 unintentionally during normal use.

This connection between the holding part 10 and the engaging part 20 is possible owing to a combination of the precise, fitting shaping of the protrusion 12 and
20 the groove 22, the precise dimensioning thereof, the tolerances which are provided and the features, in particular the elasticity properties, of the ABS plastic used.

25 Various ways of attaching a fixation profile or masking sheet consisting of one part to the fixing material were tested, and in these tests the user was able to attach and remove the attachment profile quickly and reliably, both during production itself and
30 subsequently, in order in this way, if necessary, to be able to use a different attachment profile despite the fact that, for example, it fitted better into or onto another base plate.

35 A clamping system is used in which the fixation profile was clamped around the fixing material or masking sheet and was easy to remove therefrom. A system was also tried which had a hook-and-loop strip allowing the fixation profile and the masking sheet to be mounted

and detached easily. However, both systems failed to produce sufficient holding capacity, with the result that there was a risk of the fixing or masking sheet coming loose during activation.

5

Then, a system was tried out which used screws or press-studs in order to attach the two components to one another. However, the drawback was that these screws or press-studs were large or were in the way
10 during attachment of the fixing or masking sheet 30 to the base plate 40.

Finally, tests were carried out in which the high-temperature plastic fixation profile was made from
15 two parts 10, 20, with the advantage that these parts on the one hand can be used for various fixing materials for masking sheets 30, such as low-temperature plastic, high-temperature plastic and others, and on the other hand can be used on various
20 base plates 40. Consequently, the result is a universal attachment profile 1.

According to a further embodiment (not shown), the second part 20 is attached to the first part 10 by
25 means of connecting elements, preferably screws, thus also ensuring that the two parts 10, 20 can be removed and exchanged.

The said immobilization element is, for example,
30 transparent. However, it may also be opaque.

Figure 3 diagrammatically shows a patient 50 who is to be treated and who has been placed on a fixing plate 40, in which suitable slots 41 are provided at
35 predetermined locations for inserting the engaging side 21 of the part 20 therein in a manner which is well known.

CLAIMS

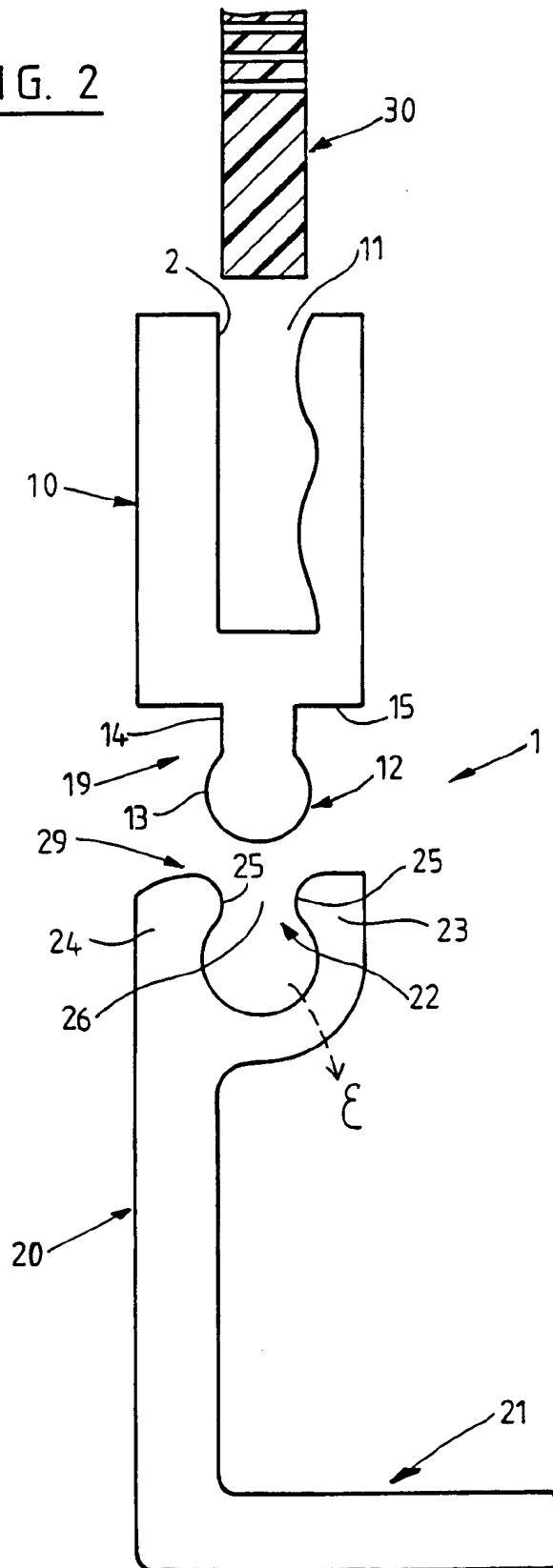
1. Fixation system for an immobilisation element of a patient, in particular a low-temperature immobilisation element comprising an attachment profile (1), one side of which is provided with a slot (11) for accommodating the said immobilisation element (30) therein, and the other side of which is provided with a fixing element (21) for interacting in a fixed manner with a base (40) as a support for the patient, characterised in that the said attachment profile (1) comprises two parts (10, 20) which can be detached from one another and which can be coupled together by means of coupling members (12, 22), which are respectively provided for this purpose on each of the two parts (10, 20), the said one part (10) being produced from a high-temperature plastic material which is non-deformable at the working temperature.
2. Fixation system according to Claim 1, characterised in that the said coupling members (12, 22) are respectively formed by a part (12) which projects with respect to the one part (10) and an associated groove (22) for accommodating the projecting part (12).
3. Fixation system according to Claim 2, characterised in that the said projecting part (12) can be snapped into the groove (22).
4. Fixation system according to Claim 2 or 3, characterised in that the said projecting part (12) can be pushed into the groove (22).
5. Fixation system according to one of Claims 2 to 4, characterised in that the projecting part (12) is joined to the said one holding part (10) in the

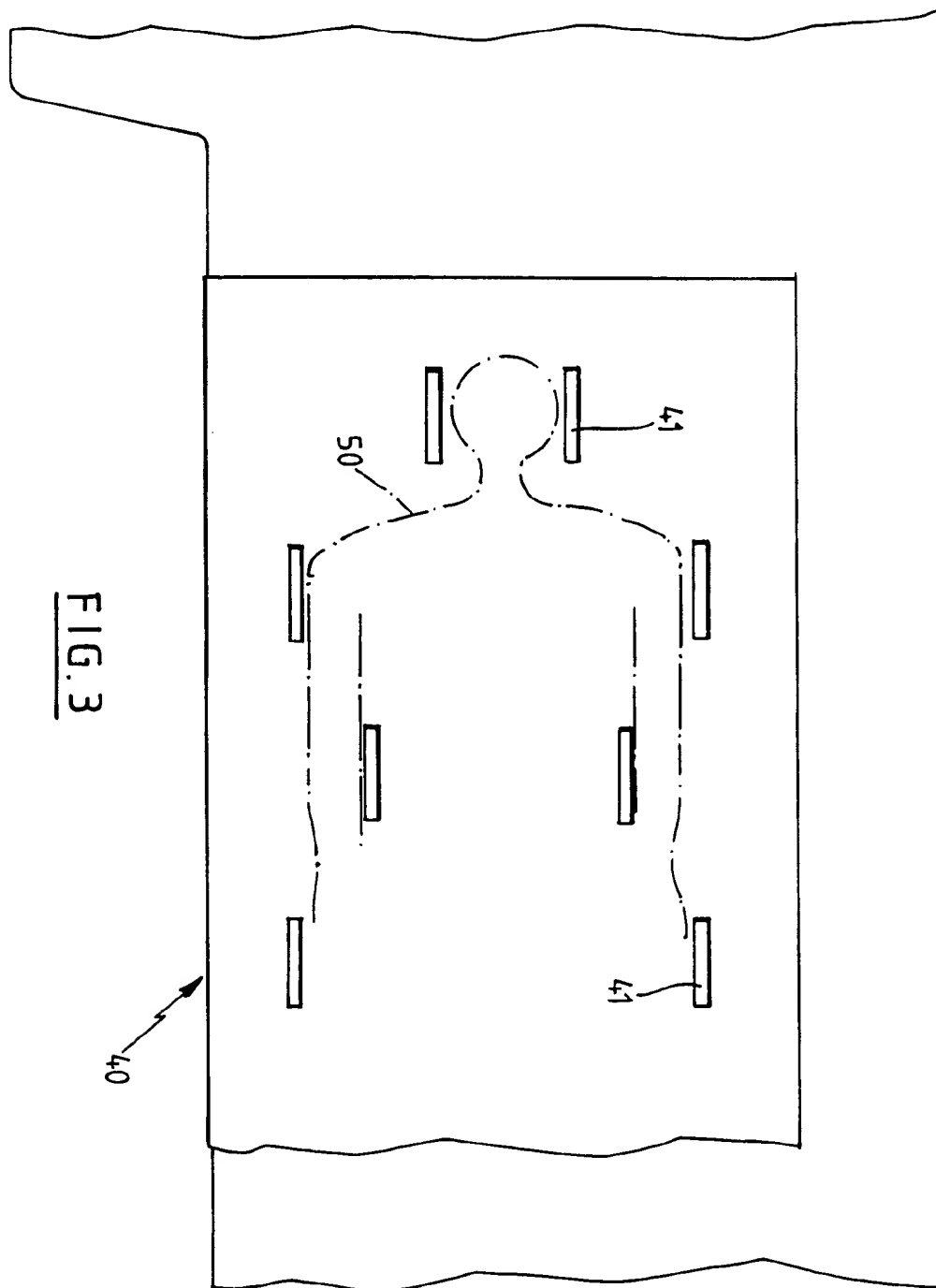
region of the bottom zone of the slot (11), and in that the groove (22) is provided at a free end of the other part (20), which is placed against the said fixing element (21).

5

6. Fixation system according to one of Claims 2 to 5, characterised in that the projecting part (12) has at its free end a bulge (13), which is joined to the bottom zone (15) of the one holding part (10) by means of a neck (14) which has a narrower cross-section than the said bulge (13).
10
7. Fixation system according to one of Claims 2 to 6, characterised in that the said groove (22) is delimited by two side walls (23, 24), at least one (23) of which is elastically deformable with respect to the other (24) in order to accommodate the projecting part (12) in the groove (22) in a dimensionally stable manner.
15
8. Fixation system according to the preceding claim, characterised in that the two side walls (23, 24) are profiled in such a manner that they protrude out (25) towards one another at their respective free ends, where they form a narrowed opening (26).
20
25
9. Fixation system according to one of the preceding claims, characterised in that both parts (10, 20) are profiled.
30
10. Fixation system according to one of the preceding claims, characterised in that the attachment profile (1) is produced from a low-density plastic, preferably from a very-low-density plastic.
35

FIG. 2





INTERNATIONAL SEARCH REPORT

Int. Application No.

PCT/BE 98/00010

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F5/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 18916 A (DOYLE KELVIN CONRAD) 1 September 1994 see page 1, line 15 - page 2, line 14; figure 3	1-10
A	WO 96 11226 A (ORFIT IND ;CUYPERS STEVEN (BE)) 18 April 1996	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

12 May 1998

Date of mailing of the international search report

22/05/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Sánchez y Sánchez, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter Application No

PCT/BE 98/00010

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9418916 A	01-09-1994	AU 6009194 A	14-09-1994
		BR 9406423 A	09-01-1996
		CA 2156185 A	01-09-1994
		CN 1118133 A	06-03-1996
		EP 0684805 A	06-12-1995
		GB 2290217 A,B	20-12-1995
		JP 8506747 T	23-07-1996
		NZ 261373 A	24-06-1997

WO 9611226 A	18-04-1996	BE 1008800 A	06-08-1996
		AU 3601995 A	02-05-1996
		EP 0802946 A	29-10-1997
